Spine Surgery Associates

Specializing in treatment of disorders of the spine

Reconstructive Cervical Surgery
Reconstructive Lumbar Surgery
Herniated Discs
Spinal Deformities
Scoliosis

Adult & Pediatric
Spine Surgery

Vance O. Gardner, MD
Fellowship Trained
Orthopedic Spine Surgeon
Qualified Medical Evaluator

Jeffrey E. Deckey, MD
Fellowship Trained
Orthopedic Spine Surgeon
Qualified Medical Evaluator

Physical Medicine &
Rehabilitation

Ali Hafezi, MD
Out Patient Physiatry
Neurodiagnostic Testing
Qualified Medical Evaluator

Cynthia T. Murphy, MD
Out Patient Physiatry
Rehabilitation

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Document Management Branch
HFA-305 Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland, 20852

REFERENCE DOCKET #: 97N-484S

To Whom It May Concern:

I am a spine surgeon and I have been in practice since 1986. When I first went into practice after a fellowship, the bone banks were just developing techniques to safely procure and process bone for effective delivery of a much-needed product for spine surgery. Patients requiring anterior fusions improved significantly with allograft bone for interbody fusion versus their own autograft iliac crest.

Harvesting the iliac crest causes a significant amount of morbidity if more than one level is harvested. In addition, autogenous iliac crest graft is many times biomechanically inferior to more cortical constructs such as allograft femur (femoral rings) or variations in that product. I was the bone bank director for the UCI Medical Center Organ and Tissue Bank in the late 1980's and worked closely with the Musculoskeletal Transplant Foundation at that time.

Since being in private practice, I have seen the development of excellent products made with allograft bone. At this time, allograft bone has created such a superior answer to anterior fusion difficulties that it would be difficult to overstate how inferior any other technique can be. Bone within the disc space for an anterior fusion is the most natural product. Cages and other techniques have been developed lately, but in my practice, they do not satisfy the criteria for consistent solid arthrodesis done safely.

Therefore, I urge the Food and Drug Administration to reconsider the possible regulation of allograft bone as a medical device. These truly are not medical devices, but tissue transplant products. If you would like, I could have testimonials of patients who have undergone

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successful arthrodesis with allograft bone and to help explain how this product has greatly enhanced their lives. It is my opinion that further regulation into the practice of safe spinal surgery could result in serious consequences resulting in inferior patient care.

If you have any questions, please feel free to call.

Sincerely,

Vance O. Gardner, M.D.
Diplomate, American Board
of Orthopaedic Surgery

VOG:jt

GARDNER & WHITE
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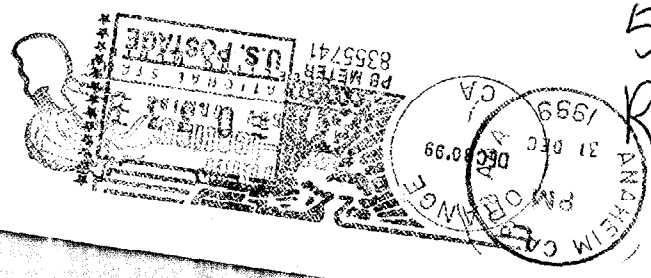

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